Zydus receives final approval from the USFDA for Sirolimus Tablets, 1 mg and 2 mg

Ahmedabad, India, 17 February, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates hereafter referred to as "Zydus") has received final approval from the United States Food and Drug Administration (USFDA) for Sirolimus Tablets, 1 mg and 2 mg (USRLD: Rapamune Tablets).

Rapamune is used to prevent rejection (anti-rejection medicine) in people 13 years of age and older who have received a kidney transplant. It is also given to treat a rare lung disorder called lymphangioleiomyomatosis which predominantly affects women of childbearing age. The drug will be manufactured at the group's formulation manufacturing facility at Moraiya.

Sirolimus Tablets had annual sales of USD 69mn in the United States (IQVIA MAT Dec. 2022).

The group now has 342 approvals and has so far filed over 440* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2022)

***

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
(formerly known as Cadila Healthcare Limited)
Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878